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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/776, 044 02/26/97 BYWATER

M 1614-178P

002292 HM12/0607  
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EXAMINER

HOLLERAN, A

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED:

06/07/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. 08/776,044	Applicant(s) Bywater et al.
Examiner Anne Holleran	Group Art Unit 1642

Responsive to communication(s) filed on Mar. 13, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 1-10, 14, and 15 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-10, 14, and 15 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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**DETAILED ACTION**

1. This communication is responsive to the Amendment filed Mar. 13, 2000. Claims 11 and 13 were canceled.

Claims 1-10, 14 and 15 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections Maintained:***

3. The rejection of Claims 1-11, 13, 14 and 15 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained in part.

With regard to the rejection of claims 11 and 13, Applicant's cancellation of the claims renders the rejection moot. With regard to claims 1-10, 14 and 15, Applicant argues that claims reciting limitations wherein the complete coding region of p53 is determined are supported by the specification because the specification discloses the complete coding sequence for human p53. However, Applicant's arguments are not found persuasive because adequate support for claims to methods where sequencing of the complete coding region is critical to the practice of the claimed

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invention is required. The specification contemplates analyzing mutations “at least throughout the part or parts of the p53 gene” (see page 8, first full paragraph). While this disclosure does not rule out methods wherein the complete coding region is sequenced it does not contemplate the claimed species of method where the complete coding sequence of p53 is determined. Thus, the rejection of claims 1-11, 13, 14 and 15 under 35 U.S.C. 112, first paragraph is maintained.

4. The rejection of Claims 1-10 and 14 under 35 U.S.C. 103(a) as being unpatentable over Elledge et al. (Breast Cancer Res. Treat. 27: 95-102, 1993) and of Callahan (J. Natl. Cancer Institute, 84: 826-827, 1992) in view of Diamandis et al (U.S. Patent No. 5,552,283) is maintained.

Applicant argues that none of the references teach methods comprising a step where the complete coding sequence of p53 is determined. This is not found persuasive as Diamandis et al clearly report (column 2, lines 13-26) that both genomic and cDNA sequences of p53 has been sequenced in methods to analyze p53 mutations. Clearly the teachings of Diamandis et al that improved accuracy is obtained with sequencing larger sized regions of the p53 gene render the claims obvious over the prior art as a whole. Thus, the rejection of claims 1-10 and 14 as obvious over the prior art is maintained.

5. The rejection of claims 11, 13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Diamandis et al (U.S. Patent No. 5,552,283) is maintained with respect to claim 15 and withdrawn with respect to claims 11 and 13.

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Cancellation of claims 11 and 13 has rendered the rejection moot. However, with respect to claim 15, as discussed above, Diamandis clearly teach that both genomic and cDNA sequence of p53 have been sequenced in methods to analyze p53 mutations. Thus, the rejection of claim 15 under 35 U.S.C. 102(e) as being anticipated by Diamandis et al is maintained.

***Claim rejections withdrawn:***

6. The rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by Hollstein et al. (Science 253: 49-53, 1991) is withdrawn in view of Applicant's amendment canceling claim 11.
  
7. The rejection of claims 11 and 13 under 35 U.S.C. 102(b) as being anticipated by Hedrum et al (BioTechniques 17: 118-129, 1994) is withdrawn in view of Applicant's amendment canceling claims 11 and 13.

***Priority:***

8. In view of the discussion of new matter, above, the denial of priority under 35 U.S.C. 119(a-e) is maintained.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Art  
Anne L. Holleran  
Patent Examiner  
June 5, 2000

*Yvonne Eyer*  
YVONNE EYLER, PH.D  
PRIMARY EXAMINER